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EXAMINER

NICHOLS, CHRISTOPHER J

ART UNIT	PAPER NUMBER
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1647

DATE MAILED: 04/26/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/724,319	Applicant(s) SCHENK, DALE B.	
	Examiner Christopher J Nichols, Ph.D.	Art Unit 1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 January 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 54-83,85,86,89,92-94,97,99 and 101-163 is/are pending in the application.
- 4a) Of the above claim(s) 54,55,83 and 101-163 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 56-82,85,86,89,92-94,97 and 99 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 54-83,85,86,89,92-94,97,99 and 101-163 are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 27 November 2000 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of Group V (claims 56-82, 85, 86, and 92-94) in the Response and Amendment filed 7 January is acknowledged. The request to rejoin Groups V and VI is hereby *granted*. Claims 56-82, 85, 86, 92-94, 97, and 99 are under examination. The remaining restriction requirement is still deemed proper and is therefore made FINAL.

Status of Application, Amendments, and/or Claims

2. The Preliminary Amendment filed 20 August 2001 has been received and entered in full.
3. The Application Data Sheet filed 20 August 2001 has been received and entered in full.
4. The Preliminary Amendment filed 27 August 2001 has been received and entered in full.
5. The Preliminary Amendment filed 30 August 2002 has been received and entered in full.

Specification

6. The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code (pp. 6 line 19). Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01.

Drawings

7. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they include the following reference sign(s) not mentioned in the description: 15A-15E are not included in the Specification. A proposed drawing correction, corrected drawings, or amendment

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to the specification to add the reference sign(s) in the description, are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

Double Patenting

Provisional Non-Statutory Double Patenting Rejection

The non-statutory double patenting rejection, whether of the obviousness-type or non-obviousness-type, is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent. In re Thorington, 418 F.2d 528, 163 USPQ 644 (CCPA 1969); In re Vogel, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); In re Van Ornum, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); In re Longi, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); and In re Goodman, 29 USPQ2d 2010 (Fed. Cir. 1993).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(b) and (c) may be used to overcome an actual or provisional rejection based on a non-statutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.78(d).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

8. Claims **56-82, 85, 86, 89, 92-94, 97, and 99** are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims **1-30** of Application No. 09/580015. Although the conflicting claims are not identical, they are not patentably distinct from each other because instant claims are either anticipated by, or would have been obvious over the '015 claims.

9. Instant claims are drawn to a method of preventing or treating a disease characterized by amyloid deposit in a patient comprising administering an effective dosage of an antibody that

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specifically binds to the amyloid deposit or component thereof to the patient, wherein the antibody specifically binds to an epitope within residues 13-28 of A β and said antibodies in a pharmaceutical composition. The '015 claims are drawn to a method of preventing or treating an amyloidogenic disease in a patient comprising administering to the patient an effective dosage of an antibody that binds to a component of an amyloid deposit in the patient and said antibodies in a pharmaceutical composition. Both the instant application and the '015 claims are drawn to a method of prevention or treatment of overlapping diseases and conditions as "a disease characterized by amyloid deposit" and "amyloidogenic disease" encompass largely the same diseases. The instant claims are drawn to antibodies that specifically bind to an epitope within residues 13-28 of A β and the '015 claims are drawn to antibodies that bind a component of an amyloid deposit. A β is such a component therefore the antibodies of the instant application are a species of the genus of antibodies as claimed in the '015 application.

10. Thus, it would have been *prima facie* obvious to the skilled artisan that the claims in both instant and the '015 application would fully encompass treatment of the same diseases with nearly identical antibodies. This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

11. Claims 56-82, 85, 86, 89, 92-94, 97, and 99 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-47, 135-135, and 144-145 of Application No. 09/979701. Although the conflicting claims are not identical, they are not patentably distinct from each other because instant claims are either anticipated by, or would have been obvious over the '701 claims.

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12. Instant claims are drawn to a method of preventing or treating a disease characterized by amyloid deposit in a patient comprising administering an effective dosage of an antibody that specifically binds to the amyloid deposit or component thereof to the patient, wherein the antibody specifically binds to an epitope within residues 13-28 of A β and said antibodies in a pharmaceutical composition. The '701 claims are drawn to a method of preventing or treating a disease associated with amyloid deposits of A β in the brain of a patient comprising administering an effective dosage of an antibody that binds to A β to the patient and said antibodies in a pharmaceutical composition. Both the instant application and the '701 claims are drawn to a method of prevention or treatment of overlapping diseases and conditions as "a disease characterized by amyloid deposit" and "a disease associated with amyloid deposits of A β in the brain" encompass largely the same diseases. The instant claims are drawn to antibodies that specifically bind to an epitope within residues 13-28 of A β and the '701 claims are drawn to antibodies that bind to A β . Therefore the antibodies of the instant application are a species of the genus of antibodies as claimed in the '701 application.

13. Thus, it would have been *prima facie* obvious to the skilled artisan that the claims in both instant and the '701 application would fully encompass treatment of the same diseases with nearly identical antibodies. This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it

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pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

14. Claims **56-82, 85, 86, 89, and 92-94** are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for *a method of prophylactically or therapeutically treating Alzheimer's disease, comprising administering to the patient an effective dosage of a pharmaceutical composition comprising an antibody that specifically binds to an epitope within residues 13-28 of A β , and hereby prophylactically or therapeutically treating the patient*, does not reasonably provide enablement for *method of prevention, treating or preventing other amyloidogenic diseases*. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to **make** or **use** the invention commensurate in scope with these claims.

15. The claims are drawn very broadly to methods of treating and/or preventing an amyloid-related disease using antibodies raised against residues 13-28 of A β . The language of said claims encompasses a genus with at least 36 known diseases, as well as peptides and derivatives thereof.

16. The specification teaches that the administration of particular anti-A β antibodies is able to reduce β -amyloid levels within the brains of mice which are transgenic for PDAPP. These mice exhibit Alzheimer's type over production and build up of β -amyloid within the brain. However, as recognized in the art, these mice do not exhibit Down's Syndrome or other amyloidogenic diseases, see in particular Schenk *et al.* (1999) "Immunization with amyloid- β attenuates Alzheimer-disease-like pathology in the PDAPP mouse." Nature **400**:173-77

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(IDS#148) and Games *et al.* (9 February 1995) “Alzheimer-type neuropathology in transgenic mice overexpressing V717F β -amyloid precursor protein.” *Nature* 373(6514): 523-527

(IDS#109). Thus, the model system used in the instant Specification is not recognized as providing for teachings that are predictive of the results which would be expected for the full scope of the claims.

17. Also, “Prevention” is understood in the art to mean a total protection from disease or injury. Thus, given the high level of required effect, a high level of evidence showing prevention is also required. While the specification demonstrates a level of protection using anti-A β antibodies for passive immunization in the PDAPP mice, total prevention was not achieved.

18. The specification fails to provide any guidance for the successful treatment of all 36 known amyloid-related diseases, and since resolution of the various complications in regards to *passive* immunization treatment regimes for amyloid-related diseases is highly unpredictable, one of skill in the art would have been unable to practice the invention without engaging in undue trial and error experimentation. In order to practice the invention using the specification and the state of the art as outlined below, the quantity of experimentation required to practice the invention as claimed *in vivo* would require the *de novo* determination of the effect of anti-A β (residues 13-28) on all the 36 amyloidogenic proteins encompassed by the claims, as well as mutants, fragments, and peptides thereof (i.e. “components”), with known amyloid related proteins, signs, and symptoms to correlate with a result ranging from the alleviation of symptoms (treatment) to total prevention. In the absence of any guidance from the specification, the amount of experimentation would be undue, and one would have been unable to practice the invention over the scope claimed.

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19. The specification as filed does not provide any guidance or examples that would enable a skilled artisan to use the disclosed methods of using anti-A β (residues 13-28) antibody for all known and unknown amyloidogenic diseases. Additionally, a person skilled in the art would recognize that predicting the efficacy of using a single antibody for at least 36 different conditions based solely the performance of a single anti-A β in an Alzheimer's disease model as highly problematic (see MPEP §2164.03). Thus, although the specification prophetically considers and discloses general methodologies of using the claimed methods, such a disclosure would not be considered enabling since the state of the treatment of amyloid-related diseases as highly unpredictable. The factors listed below have been considered in the analysis of enablement [see MPEP §2164.01(a) and *In re Wands*, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988)]:

- (A) The breadth of the claims;
- (B) The nature of the invention;
- (C) The state of the prior art;
- (D) The level of one of ordinary skill;
- (E) The level of predictability in the art;
- (F) The amount of direction provided by the inventor;
- (G) The existence of working examples; and
- (H) The quantity of experimentation needed to make or use the invention based on the content of the disclosure.

20. The following references are cited herein to illustrate the state of the art of amyloid-related diseases and *passive* immunization treatment regimes.

21. While the use of anti-A β antibodies wherein said antibodies are specific for an epitope comprising residues 13-28 of A β is feasible for treating Alzheimer's disease, Spooner *et al.* (13 December 2002) "The generation and characterization of potentially therapeutic A β antibodies in

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mice: differences according to strain and immunization protocol.” Vaccine **21**(3-4): 290-297 teaches that the route of administration, the regiment of administration, and the genetic background of the mouse used affects the production of anti-A β antibodies in response to A β immunization (Table 1 and 2). It is also noted that although no deleterious effects were observed, this too could be dependent upon genetic factors of the animal receiving the immunization (pp. 296). Thus uncertainty is found by use of A β as an immungen in regards to possible autoimmune reactions, general deleterious side effects, and variability in the production of anti-A β antibodies. Furthermore the Specification teaches that the 266 antibody binds to monomeric but not aggregated A β (pp. 70 lines 19-20)

22. Regarding derivatives and fragments of the 36 amyloidogenic proteins encompassed by the claims and antibodies directed against them, the skilled artisan readily recognizes that protein chemistry is an unpredictable area of biotechnology. Proteins with deletion, insertion or substitution/replacement of single amino acid residues may lead to both structural and functional changes in biological activity and immunological recognition, see in particular Skolnick & Fetrow (2000) “From genes to protein structure and function: novel applications of computational approaches in the genomic era.” Trends in Biotech. **18**(1): 34-39. For example, Jobling & Holmes (1991) “Analysis of structure and function of the B Subunit of cholera toxin by the use of site-directed mutagenesis.” Molecular Microbiology **5**(7): 1755-67 teaches a panel of single amino acid substitutions by oligonucleotide directed mutagenesis which produce proteins that differ in native conformation, immunological recognition, binding and toxicity. The skilled artisan further recognizes that immunological responses may depend upon the structural characteristics (conformation) of the particular protein (amino acid sequence) targeted.

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Thus, both biological function and immunological recognition are unpredictable properties which must be experimentally determined. Further it is noted, that for particularly small peptides, conjugation appears to be required for promoting an effective immune response. For instance, Stern *et al.* (May 1990) "Antibodies to the β -amyloid peptide cross-react with conformational epitopes in human fibrinogen subunits from peripheral blood." FEBS **264**:43-47 teaches that the anti-A β antibody, AMY 33 cross-reacts with fibrinogen (Table I, pp. 46). Thus absent sufficient guidance, an anti-A β antibody can cross-react with unrelated proteins thus requiring additional experimentation to determine which epitopes on each and every amyloid protein can be used to make and use an antibody with sufficient specificity to the protein for which it is raised.

23. Regarding components of the amyloid proteins claimed to which the anti-A β antibody is to bind, the problem of predicting protein structure in the absence of specific data (guidance) and in turn utilizing predicted structural determinations to ascertain functional aspects of the protein is extremely complex. While it is known that many amino acid substitutions are generally possible in any given protein the positions within the protein's sequence where such amino acid substitutions can be made with a reasonable expectation of success are limited. Certain positions in the sequence are critical to the protein's structure/function relationship, e.g. such as various sites or regions directly involved in binding, activity and in providing the correct three-dimensional spatial orientation of binding and active sites. These or other regions may also be critical determinants of antigenicity. These regions can tolerate only relatively conservative substitutions or no substitutions [see Wells (18 September 1990) "Additivity of Mutational Effects in Proteins." Biochemistry **29**(37): 8509-8517; Ngo *et al.* (2 March 1995) "The Protein

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Folding Problem and Tertiary Structure Prediction, Chapter 14: Computational Complexity

Protein Structure Prediction, and the Levinthal Paradox” pp. 492-495]. However, Applicant has provided little or no guidance beyond the mere suggestion of mutating, truncating, and breaking the claimed proteins into “fragments” and “peptides” to enable one of ordinary skill in the art to determine, without undue experimentation, the positions in the protein which are tolerant to change (e.g. such as by amino acid substitutions or deletions), the nature and extent of changes that can be made in these positions while remaining useful for making therapeutic antibodies.

Although the specification cites art-recognized procedures for producing and screening for active muteins and therapeutic antibodies, this is not adequate guidance as to the nature of active derivatives that may be constructed, but is merely an invitation to the artisan to use the current invention as a starting point for further experimentation. Even if an active or binding site were identified in the specification, they may not be sufficient, as the ordinary artisan would immediately recognize that an active or binding site must assume the proper three-dimensional configuration to be active, which conformation is dependent upon surrounding residues; therefore substitution of non-essential residues can often destroy activity and epitopes. This is of particular relevance when making antibodies, especially those required to practice a therapy.

The art recognizes that function cannot be predicted from suggestion alone [Bork (2000)

“Powers and Pitfalls in Sequence Analysis: The 70% Hurdle.” Genome Research **10**:398-400;

Skolnick and Fetrow (2000) “From gene to protein structure and function: novel applications of computational approaches in the genomic era.” Trends in Biotech. **18**(1): 34-39, especially p. 36

at Box 2; Doerks *et al.*, (June 1998) “Protein annotation: detective work for function prediction.”

Trends in Genetics **14**(6): 248-250; Smith and Zhang (November 1997) “The challenges of

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genome sequence annotation or 'The devil is in the details'." Nature Biotechnology **15**:1222-1223; Brenner (April 1999) "Errors in genome annotation." Trends in Genetics **15**(4): 132-133; Bork and Bairoch (October 1996) "Go hunting in sequence databases but watch out for the traps." Trends in Genetics **12**(10): 425-427]. Due to the large quantity of experimentation necessary to generate the infinite number of derivatives recited in the claims and possibly screen antibodies against the same for activity, the lack of direction/guidance presented in the specification regarding which structural features are required in order to provide antibodies with the necessary activity, the absence of working examples directed to same, the complex nature of the invention, the state of the prior art which establishes the unpredictability of the effects of mutation on protein structure and function as well as the resultant antibodies made from these mutants, fragments, and peptides, and the breadth of the claims which fail to recite any structural or functional limitations, undue experimentation would be required of the skilled artisan to make and/or use the claimed antibodies and method thereof in its full scope.

24. On the state of the prior art, Walker *et al.* (July 1994) "Labeling of Cerebral Amyloid In Vivo with a Monoclonal Antibody." Journal of Neuropathology and Experimental Neurology **53**(4): 377-383 (**IDS#169**) teaches the administration of a monoclonal anti- β -amyloid antibody (10D5) into the cerebrospinal fluid of aged monkeys (pp. 377). Following injection, the monkeys were sacrificed and their brains examined to confirm that the antibodies injected labeled A β plaques (Figures 1-5). It is noted that the monoclonal anti- β -amyloid antibody (10D5) did not disaggregate, prevent, or inhibit A β aggregation.

25. Also concerning passive immunization, Goldsby *et al.* (2002) Kuby Immunology 4th Ed. Chapter 18 "Vaccines" (pp. 449-465) teaches that passive immunization does not allow for the

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formation of immunological memory requiring continued dosages if the desired immunity is to be maintained. Also the issue of the antigenicity of the antibody administered must be taken into consideration because it can trigger an unwanted and possibly harmful immune response especially mouse antibodies administered to humans (pp. 451). Therefore inadequate guidance is presented in the Specification to overcome these obstacles in practicing the invention to the full scope as claimed.

26. The specification of the instant application fails to provide adequate guidance for one of skill in the art to overcome the unpredictability and challenges of applying results from treatment and risk assessment of Alzheimer's disease to other amyloidogenic disease as exemplified in the references herein. Thus, for the aforementioned reasons treatment of all amyloidogenic diseases or a treatment regiment does not appear to be commensurate in scope with the claims {see Sipe (1992) "Amyloidosis" Annu. Rev. Biochem. **61**: 947-975}.

27. Claims 57, 58, and 99 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

28. The invention appears to employ novel antibody, known as "266". Since the "266 antibody" is essential to the claimed invention they must be obtainable by a repeatable method set forth in the specification or otherwise readily available to the public. As, the specification does not disclose a repeatable process to obtain the 266 antibodies and it is not apparent if the

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266 antibodies are readily available to the public. If the 266 antibodies are not so obtainable or available, the requirements of 35 U.S.C. § 112 may be satisfied by a deposit of said antibodies.

29.

30. If the deposit is made under the Budapest Treaty, then an affidavit or declaration by Applicant, or a statement by an attorney of record over his or her signature and registration number, stating that the specific nucleic acid molecules have been deposited under the Budapest Treaty and that the 266 antibody will be irrevocably and without restriction or condition released to the public upon the issuance of a patent, would satisfy the deposit requirement made herein. If the deposit has not been made under the Budapest Treaty, then in order to certify that the deposit meets the criteria set forth in 37 C.F.R. §§ 1.801-1.809, Applicant may provide assurance of compliance by an affidavit or declaration, or by a statement by an attorney of record over his or her signature and registration number, showing that:

(a) during the pendency of this application, access to the invention will be afforded to the Commissioner upon request;

(b) all restrictions upon availability to the public will be irrevocably removed upon granting of the patent;

(c) the deposit will be maintained in a public depository for a period of 30 years or 5 years after the last request or for the effective life of the patent, whichever is longer;

(d) a test of the viability of the biological material at the time of deposit will be made (see 37 C.F.R. § 1.807); and

(e) the deposit will be replaced if it should ever become inviable.

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31. Applicant's attention is directed to M.P.E.P. §2400 in general, and specifically to §2411.05, as well as to 37 C.F.R. § 1.809(d), wherein it is set forth that "*the specification shall contain the accession number for the deposit, the date of the deposit, the name and address of the depository, and a description of the deposited material sufficient to specifically identify it and to permit examination.*" Finally, Applicant is advised that the address for the ATCC has recently changed, and that the new address should appear in the specification. The new address is:

American Type Culture Collection

10801 University Boulevard

Manassas, VA 20110-2209

32. Claims 56, 66, and 97 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The term "specifically" in claim 56 is a relative term which renders the claim indefinite. The term "specifically" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

33. Claim 86 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The term "heterologous" in claim 86 is a relative term which renders the claim indefinite. The term "heterologous" is not defined by the claim, the specification does not

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provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

34. Claims 97 and 99 are rejected under 35 U.S.C. 102(a) and 102(e) as being anticipated by US 5,593,846 (14 January 1997) Schenk *et al.*

35. The claims recite a pharmaceutical composition of an antibody which specifically binds to an epitope within residues 13-28 of A β and wherein said antibody is designated as “266”.

36. US 5,593,846 teaches an antibody whose epitope lies within residues 13-28 of A β and is known as 266 thus meeting the limitations of claims 97 and 99 (Col. 4 lines 60-67; Col. 5 lines 1-5, 28-35; Col. 13 lines 35-40; Col. 14 lines 13-28; claim 7).

37. The recitation in the claims “pharmaceutical composition” is interpreted as an intended use and is not given patentable weight in this art rejection. Also, the composition of US 5,593,846 is not inconsistent with such a composition.

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Summary

38. No claims are allowed.

39. The following articles, patents, and published patent applications were found by the Examiner during the art search while not relied upon are considered pertinent to the instant application:

- a. US 2004/0043418 A1 (4 March 2004) Holtzman *et al.*

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Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Christopher James Nichols, Ph.D.** whose telephone number is **(571) 272-0889**. The examiner can normally be reached on Monday through Friday, 8:00 AM to 6:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, **Gary Kunz, Ph.D.** can be reached on **(571) 272-0887**.

The fax number for the organization where this application or proceeding is assigned is **703-872-9306**.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at **866-217-9197** (toll-free).



CJN
April 21, 2004

ELIZABETH KEMMERER
PRIMARY EXAMINER